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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,696	10/09/2000	Tongtong Wang	210121.455C13	3927

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1633	6

DATE MAILED: 11/15/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/685,696	Applicant(s) WANG ET AL.	
	Examiner Shin-Lin Chen	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 12-15, 17-22 and 31, drawn to an isolated polypeptide comprising at least an immunogenic portion of a lung tumor protein, or a variant thereof, a pharmaceutical composition comprising said polypeptide, a fusion protein comprising at least one polypeptide according to claim 1, a pharmaceutical composition comprising said fusion protein, a vaccine comprising an immunostimulant and at least a polypeptide according to claim 1 or 12, and a method for inhibiting the development of a cancer in a patient by using said pharmaceutical composition, classifiable in classes 514, 424 and 530, subclasses 2, 192.1 and 350, respectively.

II. Claims 4-10, 16-22 and 31, drawn to an isolated polynucleotide encoding a lung tumor protein, a variant thereof, or at least 15 amino acid residues of a lung tumor protein, or a variant thereof, a polynucleotide complementary to said isolated polynucleotide, an expression vector comprising said polynucleotide, a host cell containing said vector, a pharmaceutical composition containing said polynucleotide, a method for inhibiting the development of a cancer in a patient by using said pharmaceutical composition, an isolated polynucleotide encoding a fusion protein according to claim 12, a pharmaceutical composition comprising said polynucleotide, a vaccine comprising an immunostimulant and at least a

polynucleotide according to claim 4 or 16, and a method for inhibiting the development of a cancer in a patient by using said vaccine or pharmaceutical composition, classifiable in classes 536, 424 and 514, subclasses 23.5, 184.1 and 44, respectively.

III. Claims 11, 17-22, 31 and 54-57, drawn to an isolated antibody or an antigen-binding fragment thereof that specifically binds to a lung tumor protein comprising the amino acid sequence encoded by the polynucleotide sequence as recited in the claim, a pharmaceutical composition comprising said antibody, a method for inhibiting the development of a cancer in a patient by using said pharmaceutical composition, a vaccine comprising an immunostimulant and at least an antibody according to claim 11, a method for inhibiting the development of a cancer in a patient by using said vaccine, and a diagnostic kit containing the antibody according to claim 11, classifiable in classes 530, 435 and 424, subclasses 387.1, 810 and 130.1, respectively.

IV. Claims 23-31, drawn to a pharmaceutical composition comprising an antigen-presenting cell expressing the polypeptide of claim 1, a vaccine comprising said antigen-presenting cell, and a method for inhibiting the development of a cancer in a patient by using said antigen-presenting cell, classifiable in classes 435 and 424, subclasses 372.2 and 184.1.

V. Claims 32-34 drawn to a method of removing tumor cells from a biological sample by contacting said biological sample with T cells that specifically react with a lung tumor protein, and a method for inhibiting the development of a cancer in a patient by using a biological sample treated according to the method of claim 32, classifiable in classes 435 and 424, subclasses 372.3 and 93.7, respectively.

VI. Claim 35, drawn to a method for stimulating and/or expanding T cells specific for a lung tumor protein, or a variant thereof, by using a polypeptide as recited in the claim, classifiable in classes 514 and 435, subclasses 2 and 372.3, respectively.

VII. Claim 35, drawn to a method for stimulating and/or expanding T cells specific for a lung tumor protein by using a polynucleotide encoding the polypeptide of group VI, classifiable in classes 424 and 435, subclasses 93.21 and 372.3, respectively.

VIII. Claims 35, drawn to a method for stimulating and/or expanding T cells specific for a lung tumor protein by using an antigen presenting cell that expresses a polypeptide of group VI, classifiable in classes 424 and 435, subclasses 93.7 and 372.2, 372.3, respectively.

IX. Claims 36-39, drawn to isolated T cells, and a method for inhibiting the development of a cancer in a patient by using the proliferating T cells after exposure to a polypeptide, classifiable in classes 514 and 435, subclasses 2 and 372.3, respectively.

X. Claims 36-39, drawn to isolated T cells, and a method for inhibiting the development of a cancer in a patient by using the proliferating T cells after exposure to a polynucleotide, classifiable in classes 424 and 435, subclasses 93.21 and 372.3.

XI. Claims 36-39, drawn to isolated T cells, and a method for inhibiting the development of a cancer in a patient by using the proliferating T cells after exposure to antigen presenting cells, classifiable in classes 424 and 435, subclasses 93.7 and 372.2, 372.3, respectively.

XII. Claims 40-47, drawn to a method for determining the presence or absence of a cancer in a patient by using a binding agent, such as an antibody, that binds to a lung tumor protein, classified in class 435, subclass 7.1.

XIII. Claims 48-53 and 58-60, drawn to a method for determining the presence or absence of a cancer in a patient by using oligonucleotide that hybridizes with a polynucleotide encoding a lung tumor protein, said oligonucleotide, and a diagnostic kit containing said oligonucleotide, classifiable in classes 536 and 435, subclasses 24.3 and 6, 810, respectively.

Claims 17-22 link(s) inventions I-III. Claim 31 links to inventions I-IV. Claim 35 links to inventions VI-VIII. Claims 36-39 links to inventions IX-XI The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 17-22, 31 and 35-39. Upon the allowance of the linking claim(s), the restriction requirement as to the

linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P.. § 804.01.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-III are distinct from each other because they are drawn to compositions having different chemical structure, physical properties and utilities, and requiring separate search: polypeptide, polynucleotide and antibody. Search for polynucleotide does not require search for either polypeptide or antibody, search for polypeptide does not require search for antibody or polynucleotide. Since the classification for each is different, the search for each group would not be coextensive. They are not obvious variants and deemed patentably distinct.

Group IV is distinct from groups I-III because they are drawn to compositions having different chemical structure, physical properties and biological function, and requiring separate search: antigen-presenting cells vs. polypeptides, polynucleotides and antibodies. They have

different classifications and require separate search. They are not obvious variants and deemed patentably distinct.

Groups VI-VIII are distinct from each other because they are drawn to materially different methods using compositions having different chemical structure, physical properties and biological function, and requiring separate search: polypeptides, polynucleotides and antigen-presenting cells. They have different classifications and require separate search. They are not obvious variants and deemed patentably distinct. Similarly, groups IX-XI are distinct from each other for the same reasons as discussed above.

Groups VI-VIII are distinct from groups IX-XI because they are drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. A method for stimulating and/or expanding T cells specific for a lung tumor protein and a method for inhibiting the development of a cancer in a patient by using the proliferating T cells are different methods with different objectives, different reagents and/or dosages, different method steps and response variables. Thus, groups VI-VIII are patentably distinct from groups IX-XI and require separate search.

Groups V, VI-XI, XII and XIII are distinct from each other because they are drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. A method of removing tumor cells from a biological sample, a method for stimulating and/or expanding T cells specific for a lung tumor protein and a method for inhibiting the development of a cancer in

a patient by using the proliferating T cells, and a method for determining the presence or absence of a cancer in a patient by using a binding agent, such as an antibody or an oligonucleotide, are different methods with different objectives, different reagents and/or dosages, different method steps and response variables. Thus, groups V, VI-XI, XII and XIII are patentably distinct from each other. They have different classifications and require separate search.

Groups V-XIII are distinct from groups I-IV because they are drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. A method of removing tumor cells from a biological sample, a method for stimulating and/or expanding T cells specific for a lung tumor protein, and a method for determining the presence or absence of a cancer in a patient by using a binding agent, such as an antibody or an oligonucleotide, are different from a method for inhibiting cancer development in a patient and they have different objectives, different reagents and/or dosages, different method steps and response variables. Further, a method for inhibiting the development of a cancer in a patient by using a biological sample is different from a method for inhibiting cancer development in a patient by using polynucleotide, polypeptide, or an antibody because different reagents and/or dosages and different method steps are used, and different response variables and criteria of success are expected. Thus, groups V-XIII are patentably distinct from groups I-IV. They have different classifications and require separate search.

Upon election of a group, a further restriction is required as follows:

Since the SEQ ID Nos recited in the claims of the present application were isolated by a subtractive hybridization of a cDNA library prepared from human squamous carcinoma and a cDNA library prepared from human normal lung tissues, they represent different and distinct DNA sequences derived from different genes. The chemical structures of different genes are different from each other and their gene product functions also differ from each other. Thus, the SEQ ID Nos recited in the claims of the present application are patentably distinct from each other and require separate search. Applicant is required to elect a **single** SEQ ID No. for consideration by examiner

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.